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10/560,636	12/13/2005	Michael Reinhold Kaus	DE030208US1	6806
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			DRENNAN, BARRY T	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 10/560,636 KAUS ET AL. Office Action Summary Examiner Art Unit Barry Drennan 2624 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 26 January 2009. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-20 is/are pending in the application. 4a) Of the above claim(s) _____ is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 1-20 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

1) Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (FTO/S5/08)
 Paper No(s)/Mail Date _______.

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

6) Other:

5 Notice of Informal Patent Application

Application/Control Number: 10/560,636 Page 2

Art Unit: 2624

DETAILED ACTION

Response to Amendment

 The amendment filed 26 January 2009, in response to the Office action mailed on 24 September 2008, has been entered, adding claims 9-20. Accordingly, claims 1-20 are pending in the application.

Response to Arguments

- Applicant has amended the title in response to the objection concerning the
 previous title's lack of descriptiveness. The new title is satisfactory, and accordingly,
 the corresponding objection is withdrawn.
- 3. Applicant has indicated that the section headings, the lack of which Examiner objected to, are optional under 37 CFR 1.77(b) and MPEP 608.01(a). Examiner agrees, and therefore withdraws the objection, although Examiner still recommends adding the section headings for added clarity.
- 4. Applicant has amended claims 1, 2, 5, 7, and 8 to alleviate the confusion caused by attaching the label "first" to an image that comes second in time order, and vice versa, rendering Applicant's traversal moot. Accordingly, the objection to these claims on this basis is withdrawn.
- Applicant has amended claim 6 to alleviate the objection raised under 37 CFR
 1.75(c) for failure of a dependent claim to limit a previous claim. Accordingly, the objection to this claim on this basis is withdrawn.

Art Unit: 2624

- 6. Applicant has amended claim 8 to alleviate the rejection raised under 35 USC 101 for being directed to nonstatutory subject matter (i.e., functional descriptive material). Examiner construes the "computer-readable medium" to mean statutory physical media "such as a CD-ROM," as found in the present specification on page 3, and to specifically exclude networks and other transmission- or signal-based intangible media, as these are nonstatutory (these were not described in the specification as being "computer-readable media" but were categorized separately). Accordingly, the rejection to claim 8 under 35 USC 101 is withdrawn.
- Applicant's arguments with respect to claims 1-8 under 35 U.S.C. 102(b) and
 103(a) have been considered but are moot in view of the new ground(s) of rejection.

However, Examiner notes that the argument concerning the reference McInerney, on page 9 of Applicant's arguments, is not convincing because the reference does in fact disclose a shape model of the current image. The shape model arises from the mesh elastic energy in Eq. 1 and the inflation force of Eq. 30, which, combined, result in a default state for the balloon model. This default state contributes to the internal energy calculation at each step, regardless of how the balloon is stretched in the interim, and constitutes the shape model indicated in Claim 1.

 New grounds of rejection not necessitated by Applicant's amendment are being raised under 35 U.S.C. 101 and 103(a). Consequently, this rejection is non-final. Application/Control Number: 10/560,636 Page 4

Art Unit: 2624

Claim Rejections - 35 USC § 101

9. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

tatutory categories of invention. The Federal Circuit¹, relying upon Supreme Court precedent², has indicated that a statutory "process" under 35 U.S.C. 101 must (1) be tied to a particular machine or apparatus, or (2) transform a particular article to a different state or thing. This is referred to as the "machine or transformation test", whereby the recitation of a particular machine or transformation of an article must impose meaningful limits on the claim's scope to impart patent-eligibility (See *Benson*, 409 U.S. at 71-72), and the involvement of the machine or transformation in the claimed process must not merely be insignificant extra-solution activity (See *Flook*, 437 U.S. at 590"). While the instant claim(s) recite a series of steps or acts to be performed, the claim(s) neither transform an article nor positively tie to a particular machine that accomplishes the claimed method steps, and therefore do not qualify as a statutory process.

That is, there is no machine required to perform the steps in the claims.

Furthermore, there is no eligible transformation taking place because the data being manipulated does not represent a physical object or substance (claims 1-5), and the

¹ In re Bilski, 88 USPQ2d 1385 (Fed. Cir. 2008).

Diamond v. Diehr, 450 U.S. 175, 184 (1981); Parker v. Flook, 437 U.S. 584, 588 n.9 (1978); Gottschalk v. Benson, 409 U.S. 63, 70 (1972); Cochrane v. Deener, 94 U.S. 780, 787-88 (1876).

Page 5

Application/Control Number: 10/560,636

Art Unit: 2624

manipulated data is not claimed to be depicted in any way. Note that the modification and depiction of the data must impose meaningful limits on the claim's scope, and not merely represent insignificant extra-solution activity, or an intended use or field of use.

Claim Rejections - 35 USC § 103

- 11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 12. Claims 1, 2, 4-8, and 10-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaus et al., "Automated 3D PDM Construction using Deformable Models," Proc. of 8th IEEE Int'l Conf. on Computer Vision (ICCV 2001), Vol. 1 pp. 566-572 (published July 2001, hereinafter **Kaus**), and further in view of McInerney et al., "A Dynamic Finite Element Surface Model for Segmentation and Tracking in Multidimensional Medical Images with Application to Cardiac 4D Image Analysis," Journal of Computerized Medical Imaging and Graphics, Vol. 19 No. 1, pp. 69-83 (published January 1995, hereinafter **McInerney**).
- 13. With respect to claim 1, Kaus discloses a method comprising: adapting a previous segmentation (the triangular mesh of Sec. 2.2, which is preliminarily aligned to a volumetric image and is subsequently adapted in Sec. 2.3 via an energy optimization, and thereafter is iterated, section 2.3 first

Art Unit: 2624

paragraph, such that the "previous segmentation" can refer to the result of the previous iteration) to the object in a current image (the volumetric image of Sec. 2.3), based on an energy optimization (Sec. 2.3, subsection *Energy Minimization*) that uses the mesh and a shape model for the object in the current image (the initial vertex configuration of the mesh before iteration begins; see Eq. 5 and Sec. 2.3) to determine a current segmentation for the object in the current image (the segmentation outlines shown as results in. e.g., Fig. 2).

While Kaus discloses adapting a previous segmentation of an object using the previous segmentation and the shape model (discussed above), Kaus does not disclose the previous segmentation being for a previous image.

However, McInerney discloses segmenting a previous image using a similar method and using that previous segmentation as a starting point for segmenting the current image ("We begin by fitting the model to the first volume in the sequence and use this fitted model as the starting point for the reconstruction of the LV in the next volume", Sec. 7.3, where the volumes in the sequence are "successive CT volumes in the cardiac cycle", i.e., sequential images).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Kaus by applying it to sequential images and using the result of one segmentation as a starting point for the next in the sequence as taught by McInemey, motivated by the need to track a moving body over time that would be allowed by this combination: "The tracking process allows the model

Art Unit: 2624

to be 'continuously' deformed by the time-varying external data forces induced by the stream of volume images" (McInerney, Sec. 7.3).

14. With respect to claim 2, Kaus further discloses that the energy optimization further comprises:

determining an internal energy corresponding to a first distance between the previous segmentation and the shape model (Eq. 5 in Kaus, commensurate with the equation in the present specification at p. 7 line 25, where the previous segmentation is the result of the prior iteration, or can be the result for the previous image, as disclosed by McInerney above);

determining an external energy corresponding to a second distance between the object and the previous segmentation (Eqs. 3 and 4 in Kaus, commensurate with the equations in the present specification at p. 7 lines 12 and 20); and

minimizing the external and internal energies ("The quadratic energy in Equation (2) [a weighted sum of the external and internal energies] is minimized...", Sec. 2.3, subsection *Energy Minimization*).

15. With respect to claim 4, Kaus and McInerney disclose the limitations of parent claim 1. Kaus does not specifically disclose that the object of interest is moving and/or deforming.

However, McInerney discloses that the object of interest is moving and deforming
("We can use the balloon model to estimate the nonrigid motion of the [left

Art Unit: 2624

ventricle] over successive CT volumes in the cardiac cycle," p. 79, where one of ordinary skill in the art would understand that the left ventricle both moves and deforms during the cardiac cycle).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Kaus by applying it to sequential images and using the result of one segmentation as a starting point for the next in the sequence as taught by McInerney, motivated by the need to track a moving body over time that would be allowed by this combination: "The tracking process allows the model to be 'continuously' deformed by the time-varying external data forces induced by the stream of volume images" (McInerney, Sec. 7.3).

16. With respect to claim 5, Kaus and McInerney disclose the limitations of parent claim 1. Kaus does not specifically disclose that the previous image immediately precedes the current image in the time series.

However, McInerney discloses this ("to estimate the nonrigid motion... over successive volumes" and "use this fitted model as the starting point for... the next volume," p. 79, where "volumes" corresponds to "images").

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Kaus by applying it to sequential images and using the result of one segmentation as a starting point for the next in the sequence as taught by McInerney, motivated by the need to track a moving body over time that would be allowed by this combination: "The tracking process allows the model

Art Unit: 2624

to be 'continuously' deformed by the time-varying external data forces induced by the stream of volume images" (McInerney, Sec. 7.3).

 With respect to claim 6, Kaus and McInemey disclose the limitations of parent claim 1. Kaus does not specifically disclose that the images are cardiac MR images.

However, McInerney discloses this ("CT, MRI, PET, and other noninvasive medical imaging technologies...," p. 1, and "with application to cardiac 4D image analysis," title).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Kaus by applying it to sequential images and using the result of one segmentation as a starting point for the next in the sequence as taught by McInerney, motivated by the need to track a moving body over time that would be allowed by this combination: "The tracking process allows the model to be 'continuously' deformed by the time-varying external data forces induced by the stream of volume images" (McInerney, Sec. 7.3).

18. With respect to claim 7, Kaus discloses performing the method on a Sun UltraSPARC II (Sec. 4.3), thus inherently constituting a system requiring memory for storing the images and a processor for performing the steps of the method). The remaining limitations of claim 7 are as found in claim 1, and the rationale for the rejection of claim 1 is incorporated herein. (Note that the "previous image", "current image", "orevious segmentation", and "current segmentation" of claim 1 become the

Art Unit: 2624

"first image", "second image", "first segmentation result", and "second segmentation result" of claim 2.)

- 19. With respect to claim 8, Kaus discloses performing the method on a Sun UltraSPARC II (Sec. 4.3), thus inherently requiring a computer-readable medium on which the software instructions for the method are stored). The remaining limitations of claim 8 are as found in claim 1, and the rationale for the rejection of claim 1 is incorporated herein. (Note that the "previous image", "current image", "previous segmentation", and "current segmentation" of claim 1 become the "first image", "second image", "first segmentation result", and "second segmentation result" of claim 2.)
- 20. With respect to claim 10, Kaus and McInemey disclose the limitations of parent claim 1. Kaus discloses using a shape model (see rejection of claim 1), but does not disclose predicting the next time step in the time series.

However, McInerney teaches a method of using the previous segmentation result to obtain the segmentation for the next time step in the time series (i.e., the time step subsequent to that at which the previous segmentation result was obtained, and where obtaining the segmentation constitutes a prediction; see rejection of claim 1).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Kaus by applying it to sequential images and using the result of one segmentation as a starting point for the next in the

Art Unit: 2624

sequence as taught by McInemey, motivated by the need to track a moving body over time that would be allowed by this combination: "The tracking process allows the model to be 'continuously' deformed by the time-varying external data forces induced by the stream of volume images" (McInemey, Sec. 7.3).

- 21. With respect to claim 11, Kaus further discloses including at least one of rotating or scaling the previous segmentation during the adaptation using a fast closed-form point-based registration based on singular value decomposition ("This is done by estimating R_i [rotation], t_i [translation], and s_i [scaling] using a point-based registration method based on SVD [singular value decomposition," Sec. 3).
- 22. With respect to claim 12, Kaus further discloses minimizing the energy using the equality $E = E_{ext} + (alpha)E_{int}$ where E_{ext} is the external energy, E_{int} is the internal energy, and (alpha) is a predetermined weight corresponding to a relative influence between the external and internal energies (Eq. 2 in Sec. 2.3).
- 23. With respect to claim 13, Kaus further discloses that the image processor determines an energy corresponding to a distance between the first mesh and the shape model (Eqs. 3 and 4 in Kaus, commensurate with the equations in the present specification at p. 7 lines 12 and 20).

Art Unit: 2624

- 24. With respect to claim 14, Kaus further discloses that the image processor adapts the first mesh by minimizing the energy ("The quadratic energy in Equation (2) [a weighted sum of the external and internal energies] is minimized...", Sec. 2.3, subsection Energy Minimization).
- 25. With respect to claim 15, Kaus further discloses that the image processor generates the first mesh based on the first image (via the external energy in Eq. 4) and a shape model of the object in the first image (via the internal energy in Eq. 5). This is the method of Kaus before being modified by McInerney, which does not require a mesh from an earlier time step; thus, it would be obvious to one of ordinary skill in the art to apply it to the boundary case of the first time step.
- 26. With respect to claim 16, Kaus and McInerney disclose the limitations of parent claim 3. Kaus does not disclose the first mesh including a priori time varying shape information about the object in the second image.

However, McInerney discloses using "a priori information about nonrigidity" (p. 82, col. 1, first bullet), which would become integrated into the first mesh when the first segmentation result is determined; the information would be time-varying because it would vary from one time step to the next.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Kaus by applying it to sequential images and using the result of one segmentation as a starting point for the next in the

Art Unit: 2624

sequence as taught by McInerney, motivated by the need to track a moving body over time that would be allowed by this combination: "The tracking process allows the model to be 'continuously' deformed by the time-varying external data forces induced by the stream of volume images" (McInerney, Sec. 7.3).

Page 13

- 27. With respect to claim 17, Kaus further discloses that the first mesh includes patient-specific image data (the segmentation results determined by Kaus are developed from CT scans of patients, thereby comprising patient-specific image data, e.g., Sec. 4.1 Vertebra Study).
- 28. With respect to claim 18, Kaus further discloses determining an energy corresponding to a distance between the first segmentation result and the shape model (Eq. 5 in Kaus, commensurate with the equation in the present specification at p. 7 line 25, where the previous segmentation is the result of the prior iteration, or can be the result for the previous image, as disclosed by McInerney above) and minimizing the energy to adapt the first segmentation result and the shape model to the object in the second image ("The quadratic energy in Equation (2) [a weighted sum of the external and internal energies] is minimized…", Sec. 2.3, subsection *Energy Minimization*).
- With respect to claim 19, Kaus further discloses that the computer executable instructions cause the processor to generate the first mesh based on the first image (via

Art Unit: 2624

the external energy in Eq. 4) and a shape model of the object in the first image (via the internal energy in Eq. 5). This is the method of Kaus before being modified by McInerney, which does not require a mesh from an earlier time step; thus, it would be obvious to one of ordinary skill in the art to apply it to the boundary case of the first time step.

30. With respect to claim 20, Kaus and McInemey disclose the limitations of parent claim 8. Kaus further discloses that the first segmentation result includes patient-specific image data (the segmentation results determined by Kaus are developed from CT scans of patients, thereby comprising patient-specific image data, e.g., Sec. 4.1 Vertebra Study), but does not specifically disclose that the first segmentation result includes a priori time varying shape information.

However, McInerney discloses using "a priori information about nonrigidity" (p. 82, col. 1, first bullet), which would become integrated into the first mesh when the first segmentation result is determined; the information would be time-varying because it would vary from one time step to the next.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Kaus by applying it to sequential images and using the result of one segmentation as a starting point for the next in the sequence as taught by McInerney, motivated by the need to track a moving body over time that would be allowed by this combination: "The tracking process allows the model

Page 15

Application/Control Number: 10/560.636

Art Unit: 2624

to be 'continuously' deformed by the time-varying external data forces induced by the stream of volume images" (McInerney, Sec. 7.3).

- 31 Claims 3 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaus and McInerney as applied to claim 1 above, and further in view of Siers et al.. "Comparison of two 3D automatic landmarking methods for a large training set of cardiac MR images," unknown publisher, available at http://citeseer.comp.nus.edu.sq/529161.html as cached PDF (believed to have been published3 no later than 20 March 2002, hereinafter Siers).
- 32. With respect to claim 3, Kaus and McInerney disclose the limitations of claim 1. Kaus further discloses the shape model being a three-dimensional surface mesh determined from a training model ("Select an arbitrary template from the set of learning shapes and triangulate the object surface", Sec. 2, where the learning shapes indicate training, and the object surface indicates three dimensions; see also Secs. 2.1 and 2.2, where the 3-d mesh is determined from the volumetric images). Kaus does not explicitly disclose the shape model being time-dependent.

However, Siers discloses (Sec. 2.2 of Siers) applying the method in Kaus (Sec. 2.1 and 2.2 of Kaus, as above) to form shape models of a time series of images ("Each cine acquisition contained... fifteen to twenty phases of the cardiac cycle." Sec. 3.1 of Siers: "The cardiac data sets were used to build PDMs with

³ Publication date based on the Internet Archive's archival of http://web.archive.org/web/20030203072746/http://www.isi.uu.nl/Meetings/tgv.html . dated 3 February 2003, indicating that the paper was presented and linked from the archived page for presentation on 20 March 2002. A copy of this documentation of the prior art date is attached to the Siers reference.

Art Unit: 2624

both procedures [including that of Kaus]," Sec. 3.2 of Siers), thus forming timedependent images.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Kaus and McInerney by using the time-series images obtained by using part of Siers's method to form a time-series of models to form the time-dependent shape model. Siers teaches that the individual images in the time-varying heart data sets were each different enough that Kaus's method of forming a shape model would need to be applied to each image in turn, indicating the need to use a time-varying shape model. Further, one of ordinary skill in the art would understand that the heart has a repeated cycle, indicating that the series of shape models derived from one cardiac cycle could be used in the method of Kaus and McInerney for subsequent cardiac cycles.

33. With respect to claim 9, the limitation "a 4D shape model" indicates that the shape model is a "time-dependent, three-dimensional surface mesh" as already recited in claim 3. Accordingly, claim 9 is rejected for the same reasons given for claim 3 above.

Conclusion

34. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Levin et al., U.S. Patent 5,768,413.

Art Unit: 2624

Fenster et al., U.S. Patent 6,111,983.

Metaxas, D. U.S. Patent 6,295,464 B1.

McInerney et al. (July 1993) "A finite element based deformable model for 3D biomedical image segmentation." SPIE Vol. 1905, pp. 254-269.

Hill et al. (September 1993) "Model-based interpretation of 3D medical images."

4th British Machine Vision Conference, pp. 339-348.

Montagnat et al. (December 1998) "Globally constrained deformable models for 3D object reconstruction." Signal Processing, Vol. 71 Issue 2, pp. 173-186.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barry Drennan whose telephone number is 571-270-7262. The examiner can normally be reached on Mon. through Thurs. 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vikkram Bali can be reached on 571-272-7415. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 2624

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/Barry Drennan/ Examiner, Art Unit 2624

/Vikkram Bali/

Supervisory Patent Examiner, Art Unit 2624